

COPD

D I G E S T

RESOURCES, RESEARCH, REPORTS, AND INFORMATION FOR PEOPLE
LIVING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Vol. 10, No. 1 • 2014

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Greetings friends,

I trust that you had an enjoyable holiday season and are settling into the New Year. We are very excited for 2014, as it marks the COPD Foundation's 10th anniversary and a decade of progress for the COPD community. Ten

years ago, resources, information, and education for COPD was scarce. Today, the COPD Foundation offers programs, education, and platforms for members of the COPD community to inform themselves and to become their own advocates in the fight against the third leading cause of death in the United States.

In December we were thrilled to be selected by the Patient Centered Outcomes Research Institute (PCORI) to create the COPD Patient Powered Research Network (PPRN). Over the next 18 months we will be participating in a unique and robust infrastructure building effort for clinical effectiveness research. The best part is, the information collected, how it is collected, and for what research it is used will be driven by the patient community. Over the coming months we will be asking for your opinions on research questions. We will also be asking you to join in this momentous effort to enroll over 100,000 individuals with COPD in PPRN. Stay tuned!

In this issue, and all issues of the *COPD Digest* this year, we will have special articles dedicated to our 10th anniversary. In this issue, we're proud to spotlight Pam DeNardo, an Associate on the C.O.P.D. Information Line (Info Line) who has been with the COPD Foundation since day one. We were honored to recognize the Info Line Associates at the 4th Annual COPD Awards and Recognition Benefit in New York City in December for their dedication and service to the COPD community. Pam was there to accept the award on behalf of all of her colleagues. You can read all about her inspiring story on Page 11.

Our feature article on Page 16 has insights from myself, Gerard Turino, M.D., COPD Foundation Board Member, Scott Cerreta, R.T., Director of Education for the COPD Foundation, and Patricia Jellen, R.N., about the progress made in the COPD community in the last 10 years. It is a piece you should be sure not to miss.

On Page 8 we feature an article that discusses the importance of pulmonary rehabilitation and Samantha Hillson, M.A., M.P.H., wrote the article on Page 27 that discusses the evolution of e-cigarettes. Both are important

and interesting articles for you to read and learn about.

On Page 24, we feature an article about Phil Everly, half of the vocal duo the Everly Brothers, who passed away earlier this year from COPD. Our Managing Editor Katelyn Turner interviewed Phil's wife, Patti, and she shared insight and stories about Phil's life and living with COPD.

Our public policy team continues to tackle Drug Access Issues, and their article is featured on Page 6. This article is vital reading for anyone living with COPD.

As you can see, this issue is focused on helping you, an individual living with COPD, become informed, learn more, and share what you've learned about COPD. Our goal, as always, is to provide researched information that helps you live your best quality of life.

The 10th anniversary articles are aimed at highlighting the monumental progress that has occurred in such a short amount of time. So much has changed in the last decade, but none of it would have been possible without the unwavering support from you, the COPD community.

Strides have been made in research, education, community events, advocacy and COPD legislation, and we thank each and every one of you for that.

You have put yourselves out there, hosted events, shared information, educated yourself, and took yourself to pulmonary rehabilitation and support groups. You are the impetus that keeps us moving forward, and we are so grateful for you. As we begin our 10th year, we are committed to expanding all of our activities and getting everyone with COPD involved at some level. We'll be launching a massive Community Outreach Campaign to mobilize the masses into joining our research registry, becoming COPD advocates and getting involved in organizing our community.

There's something for each of us to do and we need to encourage others to engage with us.

Please stay tuned this entire year for exciting issues of the *COPD Digest* still to come. We have many interesting and inspiring articles planned for 2014, as we continue to keep to our promise of educating and empowering all of you.

We provide you with the tools, but you make it happen.

To stay up-to-date on what we have planned for our anniversary year, please visit our website at: www.copdfoundation.org, or call our C.O.P.D. Information Line at 866-316-2673.

All the best to you, and here's to a healthy, happy, and prosperous 2014!

John W. Walsh

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DIGEST

RESOURCES, RESEARCH, REPORTS, AND INFORMATION FOR PEOPLE
LIVING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

COPD Digest® 2014 is published by the COPD Foundation



20 F Street NW, Suite 200A • Washington, D.C. 20001
1.866.316.COPD (2673)

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COPD Digest is published with the support of, and contributions from, organizations representing the entire COPD community.

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Your Voice on the Hill:

Drug Access Issues:
What You Need to Know



Winter Feature:

COPD Foundation Celebrates a
Decade of Progress*



Community Chronicles:

Remembering Phil Everly



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Drug Access Issues: What You Need to Know

Every COPD patient is unique. Even though patients may have the same diagnosis of COPD, their healthcare providers may use different treatments and different health management strategies to best address the overall health of the individual. Medications can be similar but they all have potentially different tolerances and side effects, making physician and patient drug choice even more critical.

Unfortunately, we are hearing of an increasing practice of insurance companies limiting medication choices to control costs. COPD patients are being forced to switch from medications that are controlling their symptoms and have been contributing to their health and wellbeing. The COPD Foundation thinks this is wrong.

Take it from COPD advocate "Maggie" who was recently forced to switch her medication for reasons outside of her control. For many years she was extremely satisfied with her treatment regimen and her COPD was well controlled. On her most recent trip to the pharmacy, she was informed that she had to switch to another drug without her physician's knowledge or counsel. Since that time, she has had multiple negative side effects and a diminished quality of life due to the switch. She does not believe she is doing as well on the new medication. Unfortunately, Maggie was not given the choice to do what was best for her own health.

This practice of eliminating access to medications that were previously paid for by insurance companies is becoming common, affecting individuals with COPD nationwide—just like COPD advocate Maggie.

So why are medications being changed or switched without physician or patient input?

How the system works:

Generally, insurance companies use many tools to help manage the cost of medications and therapies for the beneficiaries (patients) they cover. To contain costs, many insurance companies use various co-pay structures also known as "tiered benefit designs" in which patients are required to pay more for some medications over others. Another practice, "step therapy," requires patients to try one medication and fail on it before switching to another medication. Often a generic, and therefore less expensive drug, is used first before the insurance company will cover the cost for a more effective



and more expensive drug. Unfortunately, many of the tools used by insurers to cut costs are not to the benefit of the patient and can directly conflict with physician treatment recommendations.

Understanding the problem:

Most recently, the COPD Foundation has discovered that insurance companies are no longer covering multiple COPD medications in the same drug class, but instead are striking deals with pharmaceutical companies to only pay for drugs made by a single company. The result is patients and physicians may no longer have options when it comes to selecting a COPD treatment regimen tailored to control the patient's symptoms while minimizing side effects. This drug access problem is growing within the COPD community and it could have a significant impact on patients' wellbeing and continued management of their disease.

Why the COPD Foundation is concerned:

Lifelong disease management of COPD reduces symptoms, the frequency and severity of exacerbations, and improves the overall health of the patient. Because there are so many ways to manage COPD, there are multiple drugs used to treat COPD and many times multiple attempts must be made at identifying effective treatments. Trying and finding the correct medication combinations for a specific patient requires the physician and patient to have access to all drugs. Being forced to switch from a medication that is working and well tolerated when there is no guarantee that the new drug will either work as well or be as well tolerated is also unacceptable. Limiting a patient's access to drugs robs the COPD community of the opportunity to benefit from the right drug for the right patient. After all,

your insurance company is not your doctor. Only an individual with COPD and their physician can determine what treatment is best, not the insurance provider.

Our Stance:

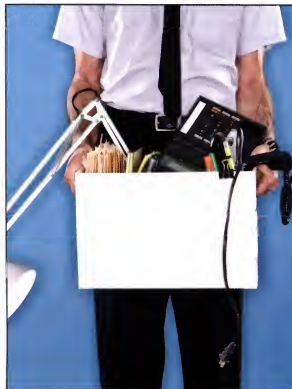
The COPD Foundation strongly condemns practices which limit treatment options that are based upon economic considerations and not quality and effectiveness. These practices are against clinical recommendations which suggest patients who have received stable disease control remain on their current medication regimen rather than switching drugs. Studies have shown that switching treatments can create unintended consequences for patients. The COPD Foundation is dedicated to strongly urging all insurers who are considering or have adopted this approach to reconsider.

The COPD Foundation has a page dedicated to educating and empowering the COPD community about this alarming new practice www.copdfoundation.org/Take-Action/Patient-Access/Access-to-Treatment. We

also encourage the entire COPD community to visit the COPD Action Center <http://actioncenter.copdfoundation.org/PatientAccess> to share their story or send a letter speaking out for the right to access all COPD drugs available, regardless of brand name. We will keep the community updated as we embark on this campaign and continue to meet with representatives of the insurance providers.

The COPD Foundation is dedicated to the needs of the COPD community, which includes access to medications and therapies. If you have experienced this drug access issue, please fill out a short survey of your experience. Your name and medical information will not be shared but your story can help us fight this problematic practice.
<https://www.surveymonkey.com/s/drugaccess2014>

"The name has been changed to protect the patient's confidentiality"



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Pulmonary Rehabilitation: The Program People with COPD Love to Hate

When you are out of breath, the idea of exercise is not the most enticing thought. However, when you weigh the benefits, both long and short term, pulmonary rehabilitation (pulmonary rehab) should be a part of most every COPD management routine.

Prior to the 1950s, the accepted treatment for COPD was to avoid situations where you might experience breathlessness. In 1952, Alvan L. Barach, M.D., authored a paper asserting that patients presently receiving oxygen therapy while enrolled in an exercise program showed significant improvement in their capacity to exercise without oxygen. It wasn't until 1969 that Thomas L. Petty, M.D., considered by many to be the father of long-term oxygen therapy, assembled a team at the University of Colorado to establish a standardized pulmonary rehabilitation program and shared this plan in his paper, "A Comprehensive Care Program for Chronic Airway Obstruction." The landmark study documented benefits including reduced hospitalizations and greater exercise tolerance in the patients who participated in the study. Not long after his study was published, the "Petty Paper," as it became known, was the model for many new pulmonary rehab programs being founded across the country.

In simplest terms, exercising will not improve your lung function, but building your other muscles trains them to use less oxygen, and allows your body to distribute its available oxygen more efficiently resulting in less breathlessness.

The theory of early rehab programs was to improve exercise tolerance, but also provide an increase in motivation, resulting in the patient having less sensitivity to being out of breath. In simplest terms, exercising will not improve your lung function, but building your other muscles trains them to use less oxygen, and allows your body to distribute its available oxygen more efficiently resulting in less breathlessness.

Some of the services now being offered for "lung affected" clients include individualized exercise programs, health monitoring and life skills training

such as breathing strategies, mobility issues, nutritional counseling, energy conservation and psychological and/or support groups. Most pulmonary rehab programs also provide their clients with exercise routines they can do at home when they no longer participate in the program.

For many individuals with COPD, their pulmonary rehab programs provide them with not only a support mechanism, but also a social outlet that encourages companionship with others experiencing the same difficulties. Another benefit reported by many participants is that the respiratory therapist in their program was able to spot an impending health problem or exacerbation before the patient was even aware there was a problem. Many pulmonary rehab programs are certified through the American Association of Cardiovascular and Pulmonary Rehabilitation with their respiratory therapists supported by the American Association for Respiratory Care.

A quality pulmonary rehabilitation program can and does offer a lifetime of benefits for those with lung impairment and success stories attest to the milestones achieved by many patients. A 9/11 worker who wanted to play with his grandchildren, a father who wanted to dance at his daughter's wedding, and a grandmother who wanted to visit a grandchild she had never met were all able to achieve their goals with the help of their pulmonary rehab program and a caring respiratory therapist.

If you are not able to participate in a pulmonary rehab program, exercise should be a regular part of your COPD management program. Talk to your health care professional about what exercises are safe and beneficial for you.

Potential gains from participation in pulmonary rehab can be tremendous. A little effort on your part will lead to valuable lifestyle changes and will result in better COPD management. 

Stay tuned for the next issue of the COPD Digest, in which we'll feature the Grace Anne Dorney Pulmonary Rehabilitation Centers in West Virginia.



This article is special for the COPD Foundation's 10-year anniversary.

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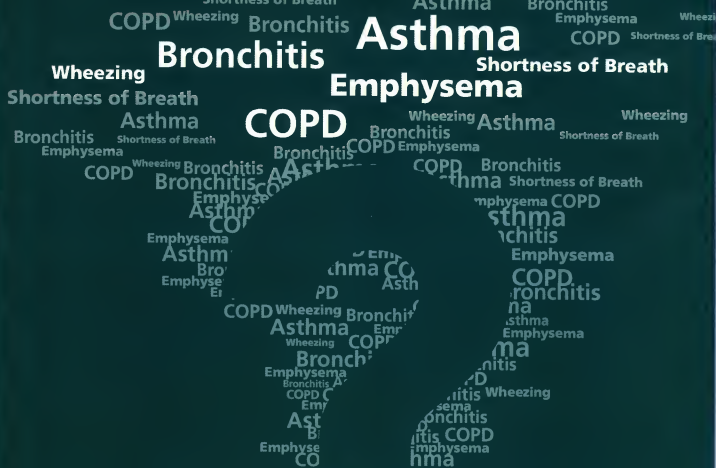


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Pam DeNardo: A Decade of Helping Individuals Living with COPD

When Pam DeNardo was diagnosed with COPD in 1999, there were scant resources available. She had to do her own research—teaching herself about medications, inhalers, and pulmonary rehabilitation, a task she said was daunting and scary without guidance or any references

“I was terrified. My doctor said that at best I had three to five years to live,” DeNardo says. “Incurable”—that’s all I could think of. Except, I couldn’t die. I was a single mother of two, I had a mother in her 90s who needed me, and a small insurance business that had just turned the corner and was making money. I simply

could not be sick, and I could not die.”

Today, DeNardo is one of 35 associates who work on the COPD Foundation’s C.O.P.D. Information Line. When it was created in 2007, they averaged 300 inbound calls every month. Today, the associates field anywhere between 5,000-6,000 contacts each month. DeNardo was one of the driving forces behind the creation of the Information Line.

“Today, patients are still scared. You can hear that when they call the Info Line. The best thing is when I get a call from a newly diagnosed patient, because I can tell them I’ve had the diagnosis for 15 years, and you can hear the relief in their voices,” she says. “The Information Line, to me, is the culmination of everything I believed in.”

In 2007, she met with Bill Clark, director of outreach programs at the COPD Foundation, and John and Diane Walsh, and together, they recruited patients, set up the toll-free line for support and information, and the Information Line was born.

Since her diagnosis, DeNardo has become a passionate advocate for COPD. In 2001 she was invited to do a speaking engagement, which turned out to be in front of Congress, including Sen. Dick Durbin (D-IL), who is now co-chair of the COPD

Congressional Caucus.

“In the beginning, people would tell me they had COPD, and that they had not told their spouse yet. Today, it’s a better-known disease. There are resources now—many of which are on the COPD Foundation website,” DeNardo says. “Doctors are giving out our phone number now. The Foundation has become our safe place—our place for information. In that way, everyone’s amazed at what’s happened in the past 10 years.

“The Foundation addresses people’s fears and encourages them to go out and enjoy themselves while wearing oxygen. Research is moving along—every single avenue—the Foundation has done it all,” DeNardo says.

DeNardo calls her fellow associates “heroes” and says they are incredible people.

“You never know what’s going to happen when you pick up that phone, but they always handle it superbly. I would love to applaud them because I think they are amazing people,” she says. “I remember when I first met John Walsh and he told me he was going to start the COPD Foundation, and said he wished more patients would speak out. He’s achieved beyond that—and has encouraged people to get out there and talk. There are 15 million people living with this disease in the U.S. 15 million—that’s enough people.”

“Just imagine how powerful it would be if each one of those patients spoke out and volunteered in some way. We would win this fight,” she says. “If patients are interested in how they can help, they should call the Information Line—we are there to guide them.”

The C.O.P.D. Information Line is open 9 a.m. to 9 p.m. EST Monday through Friday, and can be reached at: (866) 316 COPD (2673).

DeNardo says she can see a future that holds a cure for COPD. She says she can see more research happening, and more people who want to become involved in the cause.

“The Foundation will continue to grow, and I believe it [a cure] will happen. And I hope to be there. I’m working hard to be there,” DeNardo says.



Pam DeNardo



This article is special for the COPD Foundation’s 10-year anniversary.

NASCAR-Sponsored DRIVE4COPD Second Annual Golf Invitational

The COPD Foundation hosted the NASCAR-Sponsored DRIVE4COPD Second Annual Golf Invitational November 15, 2013 at the Miami Beach Golf Club. Sixty-four players participated in the event, which raised more than \$75,000 for the COPD Foundation—more than double the amount raised the previous year.

"The second annual NASCAR-Sponsored DRIVE4COPD Golf Invitational was truly a successful event," said Norris Scott, NASCAR vice president of partnership marketing. "It is an important part of NASCAR's Championship Weekend in Miami and supports the objective to raise awareness and funds for the Official Health Initiative of NASCAR."

NASCAR teams and tracks, such as Richard Childress Racing (RCR), Pocono Raceway, Bristol Motor

Speedway and Daytona Speedway contributed to the success of this year's event.

"We at RCR are proud to support our partners at COPD each year. As a racing family, we have been directly impacted by this disease and are more than happy to support," Jeremy Burleson, managing director of partnership marketing/communications at RCR, says. "It's an honor and a privilege to be involved with DRIVE4COPD and their continuing efforts to raise awareness for the third leading cause of death in the United States. RCR takes pride in our affiliation with the COPD Foundation and our support of their various fundraising efforts, namely the 2nd Annual DRIVE4COPD Golf Invitational. We're grateful for the opportunity to not only support the cause monetarily, but also to participate in what was a fantastic event!"



Left to right: Dr. Byron Thomashow, Dr. Alex White, Progressive Medical Research, Richard Johnson, Nominee for Betty Jeanne Humanitarian Award from Alpha-1, John W. Walsh



Left to right: COPD Executive Director Craig Kephart, COPD President and Co-Founder John W. Walsh, Jeff Owen, Owen Marketing, COPD Board President Dr. Byron Thomashow



Left to right: Dave Finley, NASCAR, Jase Chitwood, President of DAYTONA Speedway, John W. Walsh, Darrell Waltrip, International Speedway Corporation

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- The effect of augmentation therapy with GLASSIA or any Alpha₁-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha₁-PI deficiency has not been demonstrated in randomized, controlled clinical trials.
- Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with GLASSIA are not available.
- GLASSIA is not indicated as therapy for lung disease in patients in whom severe Alpha₁-PI deficiency has not been established.

DETAILED IMPORTANT RISK INFORMATION FOR GLASSIA

GLASSIA is contraindicated in immunoglobulin A (IgA) deficient patients with antibodies against IgA. Patients with selective or severe IgA deficiency and with known antibodies to IgA have a greater risk of developing severe hypersensitivity and anaphylactic reactions.

GLASSIA is contraindicated in individuals with a history of severe immediate hypersensitivity reactions, including anaphylaxis, to Alpha₁-PI products.

Monitor vital signs continuously and observe the patient carefully throughout the infusion. **If anaphylactic or severe anaphylactoid reactions occur, discontinue the infusion immediately.**

GLASSIA is made from human plasma and may carry a risk of transmitting infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

GLASSIA should be administered at room temperature at a rate not greater than 0.04 mL/kg body weight per minute. Administer GLASSIA within 3 hours of entering the vials.

Safety and effectiveness in patients over 65 years of age have not been established.

In the clinical studies, one subject experienced a treatment emergent serious adverse reaction (infective exacerbation of COPD), considered possibly related to treatment with GLASSIA due to its temporal association. The most common adverse reactions deemed possibly related to GLASSIA administration (>5%) were headache and dizziness.

Please see Brief Summary of Full Prescribing Information on the adjacent page.

References: 1. GLASSIA [Alpha₁-Proteinase Inhibitor (Human)] Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; June 2012. 2. ZEMARIA [Alpha₁-Proteinase Inhibitor (Human)] Prescribing Information. CSL Behring, LLC; Kankakee, IL; April 2013. 3. APALAST NP [Alpha₁-Proteinase Inhibitor (Human)] Prescribing Information. Baxter Healthcare Corporation; Westlake Village, CA; April 2010. 4. PROLASTIN-C [Alpha₁-Proteinase Inhibitor (Human)] Prescribing Information. Telectis Biotherapeutics, Inc.; Research Triangle Park, NC; January 2013. 5. ASHP guidelines on preventing medication errors in hospitals. American Society of Health System Pharmacists Web site. http://www.ashp.org/e_ashp/docs/files/MedMe_Gal_Hosp.pdf. Accessed June 18, 2013

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February 2014 USBS/341/13-0003a

Glassia
[Alpha₁-Proteinase Inhibitor (Human)]

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GLASSIA [Alpha]-Proteinase Inhibitor (Human)

Brief Summary of Prescribing Information. Please see package insert for full prescribing information.

INDICATIONS AND USAGE

Alpha-Proteinase Inhibitor (Human), GLASSIA is indicated for chronic augmentation and maintenance therapy in adults with emphysema due to congenital deficiency of alpha-proteinase inhibitor (Alpha- PI), also known as alpha $\text{-}\alpha_1$ -antitrypsin (AAT) deficiency.

- The effect of augmentation therapy with GLASSIA or any Alpha- PI product on pulmonary exacerbations and on the progression of emphysema in Alpha- PI deficiency has not been demonstrated in randomized, controlled clinical trials.
- Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy of individuals with GLASSIA are not available.
- GLASSIA is not indicated as therapy for lung disease in patients in whom severe Alpha- PI deficiency has not been established.

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- Administer GLASSIA alone; do not mix with other agents or diluting solutions.
- Administer product brought to room temperature within three hours of entering the vials.

Treatment of Congenital Alpha-Proteinase Inhibitor Deficiency

The recommended dosage of GLASSIA is 60 mg/kg body weight administered once weekly by intravenous infusion. Dose ranging studies using efficacy endpoints have not been performed. The recommended dosage of 60 mg/kg takes approximately 60-80 minutes to infuse. The infusion rate should not exceed 0.04 mL/kg body weight per minute.

CONTRAINDICATIONS

GLASSIA is contraindicated in immunoglobulin A (IgA) deficient patients with antibodies against IgA.

GLASSIA is contraindicated in individuals with a history of severe immediate hypersensitivity reactions, including anaphylaxis, to Alpha- PI products.

WARNINGS AND PRECAUTIONS

Hypersensitivity to IgA

GLASSIA may contain trace amounts of IgA. Patients with selective or severe IgA deficiency and with known antibodies to IgA, have a greater risk of developing severe hypersensitivity and anaphylactic reactions. Monitor vital signs continuously and observe the patient carefully throughout the infusion.

IF ANAPHYLACTIC OR SEVERE ANAPHYLACTOID REACTIONS OCCUR, DISCONTINUE THE INFUSION IMMEDIATELY. Have epinephrine and other appropriate supportive therapy available for the treatment of any acute anaphylactic or anaphylactoid reaction.

Transmissible Infectious Agents

Because this product is made from human plasma, it may carry a risk of transmitting infectious agents, such as viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. The risk of transmitting an infectious agent has been minimized by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections and by inactivating and removing certain viruses during the manufacturing process (see *Description* [11] in full prescribing information for viral reduction measures). Despite these measures, such products may still potentially transmit human pathogenic agents. There is also the possibility that unknown infectious agents may be present in such products.

The physician should weigh the risks and benefits of the use of this product and discuss the risks and benefits with the patient.

All infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Kamada Ltd. at 1-866-GLASSIA or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

No seroconversions for hepatitis B or C (HBV or HCV) or human immunodeficiency virus (HIV) or any other known infectious agent were reported with the use of GLASSIA during the clinical studies.

ADVERSE REACTIONS

The serious adverse reaction observed during clinical studies with GLASSIA was exacerbation of chronic obstructive pulmonary disease (COPD).

The most common drug-related adverse reactions observed by the investigator to be at least possibly related to GLASSIA administration observed at a rate of $\geq 5\%$ in subjects receiving GLASSIA were headache and dizziness.

Adverse Reactions Occurring in $\geq 5\%$ of Subjects During the First 12 Weeks of Treatment

	GLASSIA No. of subjects: 33	Prolastin No. of subjects: 17
Adverse Event (AE)	No. of subjects with adverse reactions ¹ (AR) (percentage of all subjects)	No. of subjects with adverse reactions ¹ (AR) (percentage of all subjects)
Cough	3 (9%)	4 (24%)
Upper respiratory tract infection	3 (9%)	0 (0%)
Headache	3 (9%)	3 (18%)
Sinusitis	2 (6%)	1 (6%)
Chest discomfort	2 (6%)	0 (0%)
Dizziness	2 (6%)	0 (0%)
Hepatic enzyme increased	2 (6%)	0 (0%)

¹An adverse reaction is any adverse event which met any of the following criteria:

(a) an adverse event that began within 72 hours following the end of product infusion, or
(b) an adverse event considered by either the investigator or sponsor to be at least possibly related to product administration, or (c) an adverse event for which causality assessment was missing or indeterminate

Postmarketing Experience

The following reactions have been identified during postmarketing use of GLASSIA in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. The reactions, which have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to GLASSIA, or a combination of these factors, include: Headache, Dyspnea, Fatigue and Nausea.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

Animal reproduction studies have not been conducted with GLASSIA. It is also not known whether GLASSIA can cause fetal harm when administered to pregnant women or can affect reproductive capacity. GLASSIA should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether Alpha- PI is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when GLASSIA is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established

Geriatric Use

Clinical studies of GLASSIA included 11 subjects of 65 years of age or older. This number of subjects was not sufficient to determine whether they respond differently from younger subjects. As for all patients, dosing for geriatric patients should be appropriate to their overall situation. Safety and effectiveness in patients over 65 years of age have not been established.

PATIENT COUNSELING INFORMATION

- Inform patients of the early signs of hypersensitivity reactions, including hives, generalized urticaria, chest tightness, dyspnea, wheezing, faintness, hypotension, and anaphylaxis. Advise patients to discontinue use of the product and contact their physician and/or seek immediate emergency care, depending on the severity of the reaction, if these symptoms occur.
- Inform patients that GLASSIA is made from human plasma and may contain infectious agents that can cause disease (e.g., viruses and, theoretically, the CJD agent). Explain that the risk of GLASSIA transmitting an infectious agent has been reduced by screening the plasma donors, by testing the donated plasma for certain virus infections, and by a process demonstrated to inactivate and/or remove certain viruses during manufacturing (see *Warnings and Precautions*). Symptoms of a possible virus infection include headache, fever, nausea, vomiting, weakness, malaise, diarrhea, or, in the case of hepatitis, jaundice.
- Inform patients that administration of GLASSIA has been demonstrated to raise the plasma level of Alpha- PI , but that the effect of this augmentation on the frequency of pulmonary exacerbations and on the rate of progression of emphysema has not been established by clinical trials.

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Issued October 2013 USBS341130004

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The COPD Foundation Celebrates a Decade of Progress

This year marks the 10th anniversary of the COPD Foundation, and a decade of progress that we've established, built and will continue to grow upon. This article features four different perspectives of the past decade of COPD from prominent individuals in the COPD community: COPD Foundation President and Co-Founder John W. Walsh, COPD Foundation Board Member Gerard Turino, M.D., COPD Foundation Director of Education Scott Cerretta, R.R.T, and Patricia A. Jellen, M.S.N, R.N.

Patricia A. Jellen, M.S.N., R.N.:



Ten years seems like an eternity, but in reality, the time goes very fast and so much can happen! When asked to reflect on the past 10 years as it related to COPD and me, a registered nurse, I am filled with excitement and pride. While we still face obstacles in managing and treating

COPD, I can honestly say that many positive things have happened over the past 10 years. Advances in research, advocacy and disease management have moved us in a positive direction in the COPD world.

In 2003, my primary role, as it related to COPD, was coordinating the lung volume reduction surgery (LVRS) program at New York Presbyterian Hospital-Columbia University Medical Center (NYPH/CUMC). A major part of my responsibilities between 1998 and 2003 included coordinating our institution's participation in the National Emphysema Treatment Trial (NETT). The NETT results, released in May 2003, were able to give guidance as to the role of LVRS in the treatment of emphysema. For the first time ever, we had objective information about which patients could potentially benefit from the procedure. Based on the NETT results, providers could categorize potential surgical candidates into groups to give better predictions of benefit and potential risk from LVRS. NETT defined those patients who were at increased risk of death and who should never be offered LVRS. The Centers for Medicare and Medicaid Services (CMS), utilizing NETT results, amended its coverage policy for LVRS and established clear, concise guidelines for those

beneficiaries/patients for whom the procedure of LVRS could be considered and covered.

January 2004 marked the effective date for the initiation of the national coverage policy for Medicare beneficiaries for LVRS. Since 2004, the LVRS program at NYPH/CUMC continues to evaluate and operate on patients who meet the NETT criteria. Our outcomes mirror those from NETT and we continue to look for new ways to improve the quality of the lives of the COPD patients referred to our institution.

While the number of patients who get LVRS nationwide today remains relatively low, I would say that the validation of LVRS as a potential therapy or intervention for patients with COPD has generated innovative development and research of alternate methods to achieve the same results of LVRS but with a less invasive approach.

Such awareness of research comes from the huge growth I have seen in advocacy from the COPD community over the past 10 years. Finally, those affected with COPD have resources and groups that can help them navigate an often complicated health care system and improve the management of their health or specifically their COPD. The mere fact that the COPD Foundation is where it is today is a testament to the people, patients and providers, who have remained steadfast in their belief that they can make a difference. I credit advocacy and patient awareness over the past 10 years with changes in the development of oxygen devices to allow for increased mobility; improvement in the ability to travel with oxygen; and finally with the fact that today we have a national policy for the coverage of pulmonary rehabilitation. Increased patient awareness and involvement is key.

As a nurse I know how important patient education is to outcomes, and my experience working with patients who have COPD over the past 16 years has taught me that knowledge related to medications, proper inhaler technique, signs and symptoms of an exacerbation, hand hygiene, exercise, oxygen therapy, and energy conservation is critical to outcomes in those with COPD. People must be empowered through knowledge to manage their own disease. The development and availability of educational resources for COPD has been amazing over the past decade. Such educational



This article is special for the COPD Foundation's 10-year anniversary.

materials, websites and blogs allow patients and their caregivers to learn about COPD.

Patients now are learning to LIVE with COPD, not merely exist with it.

So over the past decade, we have accomplished much but we are not done. The groundwork has been laid, now is it time that we push forward. We should not be satisfied with the status quo. We, the COPD community, must demand more. Let's go for it all—funding for the cure, stem cell research—whatever it takes to change the tide. Imagine what someone will be writing about in 2024.

Gerard Turino, M.D.:



I began my career as a pulmonary physician with a fellowship in the 1950s and was fortunate enough to have my early clinical training at the Columbia University Division at Bellevue Hospital in New York. At that time, Bellevue was a center of cardiopulmonary research in the United States and beyond. The directors of that center were Drs. Dickinson Richards and Andre Courmand who, with Werner Forsmann were the first to catheterize the human heart in patients. For this advance, they received the Nobel Prize in Medicine and Physiology in 1956.

At that time, one could characterize the clinical understanding of COPD as undefined. What understanding there was came mostly from anatomic pathology (a medial specialty that is concerned with the diagnosis of disease based on different examinations of organs and tissues), which described the presence of emphysema in lungs of patients dying with lung disease. Such a description was first recorded by the famous French pathologist Laennec in the early 1800's. Bronchi were recognized as being narrowed and inflamed and abnormalities in the structure of the elastic tissue were so noted in the early 1960's. In the 1940's and early 1950's pulmonary function tests were being developed with great precision. Lung function tests could quantify the obstruction to bronchial airflow, the lowering of the capacity for respiratory gas exchange and the changes in mechanical characteristics of the lung in terms of a loss of lung recoil. However, characterization of COPD as a clinical entity in patients var-

ied among clinicians.

The following statement appeared in the introduction to a publication on diagnostic standards from the American Thoracic Society in 1962 entitled: *Chronic Bronchitis, Asthma and Pulmonary Emphysema*.

"Because precise definitions and classifications have not been available, a tendency has developed for workers in separate disciplines to define these diseases differently by criteria selected from their specific frames of reference or by their particular methods of observation or techniques for measurements. The lack of widely accepted definitions and classifications has impaired communication which, in turn, has retarded clinical and research progress."

At that time in England, with its cold and rainy climate, chronic bronchitis was thought to be the predominant cause of lung disease because of its manifestation of daily cough and sputum. In the Netherlands, there was emphasis on allergic abnormalities and the role of airway hyper-reactivity as related to asthma. In the U.S., there was recognition that anatomical emphysema was a significant element in the disease. Smoking, as a causative factor, was not to be accepted as a toxic agent until the early 1960's.

However, a major insight into disease mechanisms came in 1963 when alpha-1 antitrypsin deficiency was discovered by Laurell and Eriksson in Sweden as a genetic abnormality associated with the development of emphysema in men and women at an early age and in the absence of exposure to tobacco smoke. This proved that there was at least one genetic cause for emphysema.

This same imbalance could be applied also to patients with COPD who had normal levels of alpha-1 antitrypsin in blood and tissue when it was shown that the increased oxidants in tobacco could actually inactivate the alpha-1 antitrypsin protein causing much the same pathology as someone with Alpha-1.

To formalize the clinical approach to COPD, the American Thoracic Society convened a workshop on definitions of COPD in 1984. This workshop was chaired by Gordon Snider and I was also a member. Out of this workshop definitions were developed which still apply today. Emphysema was defined as the destruction of alveolar structure, which had to be diagnosed by anatomical or radiological criteria. Bronchitis was defined as the presence of cough and sputum on

most days for three months each year for two years. Clinical characterization of COPD was the presence of irreversible airway obstruction with an FEV1 below 70% predicted. Along the way, a third diagnostic component was added to chronic bronchitis and emphysema under the umbrella of COPD, which is refractory asthma recognizing that some patients with persistent asthma go on to develop chronic airway obstruction.

Significant position papers on the diagnosis and treatment of COPD were published by the American Thoracic Society in 1995 and updated in 2004. Also, other highly significant position papers were published as "The Global Strategy for the Diagnosis, management and presentation of chronic obstructive pulmonary disease", first published in 2001 and revised in 2006. This GOLD Strategy, as it was called, formalized the clinical status of patients as determined by spirometric performance involving measurements of FEV1 and FEV1/FVC with gradations of mild, moderate, severe and very severe disease. The cut-off between normal and COPD is, by Gold criteria, FEV1/FVC < 70%. The GOLD criteria offered the following definition of COPD:

"Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its 'pulmonary component' is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases."

The development of the "GOLD Criteria" was significant in providing a common language for clinicians to classify patients for clinical care and projects in research.

Beginning 10 years ago, there was the realization that COPD was becoming a major public health problem, which was going unrecognized by patients and by physicians since mild or moderate forms of airway obstruction were being unrecognized by patients and attributed to weight gain, age or deconditioning. There was also the realization that COPD should best be diagnosed early to eliminate tobacco exposure and treat exacerbations.

John Walsh, an alpha-1 antitrypsin deficiency pa-

tient himself and founder of the Alpha-1 Foundation recognized that a new foundation focusing on COPD specifically, as a major public health problem nationally and internationally, could serve medicine and the public good. The COPD foundation was thus formed in the year 2004 with the mission to improve patient care, increase public awareness, augment education with respect to COPD among physicians and medical personnel and promote research to increase understanding COPD to achieve a cure. From its beginning the COPD Foundation worked cooperatively with the American Thoracic Society, the National Heart, Lung and Blood Institute, the FDA and pharma to achieve these goals. A major early step of the Foundation was the formation of the COPD gene study under the direction of Dr. Edwin Silverman and Dr. James Crapo which involved the registration of 10,000 patients with COPD whose genetic status, pulmonary function and radiological status by computed tomography were characterized.

Under the present leadership of Dr. Byron Thomashaw and a dedicated Board of Directors, the COPD Foundation has instituted programs to assist patients with COPD in their immediate care, furthered the search for useful biomarkers of the disease, clarified comorbidities and increased public awareness of the disease internationally where environmental pollutants in the home are etiological agents.

There is recognition that COPD clinically presents mixed patterns of disease with variations in the presence and severity of emphysema, bronchitis and the state of tissue inflammation. One of the major problems in understanding COPD is determining what mechanisms cause progression of COPD once initiating mechanisms such as exposure to tobacco smoke have ceased. Overall, the answer to this problem may await a deeper understanding of the genetic, cellular and molecular mechanisms that underlie the continued inflammatory state of the lung after initiating factors have been eliminated. Hopefully investigations into the injurious mechanisms, which may involve proteases and antiproteases, along with genetic predispositions, may progress in the coming years to give a clearer picture of the mechanisms, which determine the severity and progression of the disease and the re-

sistance to treatment.

With the necessary financial support, the COPD Foundation can continue to be a leader in the effort to seek a cure, improve patient care and increase awareness.

Scott Cerreta, B.S., R.R.T.:



Informing and educating individuals impacted by COPD has been a main goal of the COPD Foundation since it was established in 2004. There have been many changes in this department over the last 10 years, with an eye on continual growth well into the future.

In 2004, we started with educational materials for patients including *The What's of COPD*, *The 1s, 2s and 3s of COPD* and *COPD fact sheets*. In 2007 we introduced the *Big Fat Reference Guide® (BFRG)*, a 400+ page manual for living well with COPD. Today, our educational materials are more robust with tools for health care professionals including the very popular *Pocket Consultant Guide (PCG)*. The PCG is a guide for the health care professional to properly diagnose and treat COPD.

While it is a comprehensive and valuable reference, the BFRG is not practical for daily use. With this in mind, in 2010 the *Slim Skinny Reference Guides® (SSRGs)* were created. This is a series of the 10 most salient topics taken from the BFRG, pared down, and put into 12 to 16-page easy-to-read booklets. The SSRG series is great for patient support groups, pulmonary rehabilitation centers and inpatient hospital systems. In the last three years we have added a new booklet to the SSRG series, *COPD in the Hospital and the Transition Back to Home*. We also introduced the *Disaster Preparedness Plan kit* in 2013.

To increase the distribution of educational materials in 2011 we introduced the online catalogue. As always, individuals and family members impacted by COPD can continue to order free educational materials with free shipping by calling the COPD Information Line at 1-866-316-COPD (2673). In response to demand from health care professionals working in hospitals and clinics, we created a special ordering portal enabling organizations to distribute our materials directly to

their patients. While these educational materials remain free, we do charge shipping fees to these organizations. Doing this helps the COPD Foundation to keep costs under control while continuing to make educational materials accessible to all those who need them. In 2011 we averaged 10 orders a month. Today, we average 20 orders a week.

As a national organization, the COPD Foundation has been expanding our borders outside of the United States, working on an international presence since 2010. This led us to the translation of our three most common educational materials: the BFRG, SSRGs, and *The 1's, 2s and 3's of COPD*. This work was completed in 2013 and includes nine languages in addition to English: Arabic, Chinese, French, German, Hindi, Italian, Japanese, Portuguese and Spanish.

With the introduction of our new website in 2013, we added all of our educational materials for free download furthering easy access for patients and health care professionals free of charge. The COPD Foundation remains one of a few organizations continuing to provide educational materials at no cost. In addition to free downloads, our website hosts an educational video library. Videos include *COPD 101*, a fascinating video tutorial on what happens to the lungs during COPD and why people are short of breath during simple activities, as well as inhaler training tutorials.

What about programs? The Pulmonary Education Program (PEP) is our most recent and successful. Launched in the fall of 2012, this program pre-packages COPD Foundation educational materials for partnering pulmonary rehabilitation centers to distribute to qualified COPD patients in their pulmonary rehabilitation programs. To date, we have over 210 pulmonary rehabilitation centers enrolled in PEP. Patients who graduate from a PEP pulmonary rehabilitation center may continue with support, encouragement and accountability by joining *On Track with COPD*. Pulmonary rehab graduates who join *On Track* receive a phone call once a month for 24 months from a trained infoline associate who provides encouragement and coaching to continue learning and staying healthy with COPD.

Over the past 10 years the COPD Foundation's education department has grown in many ways, but

always with one mission in mind - to benefit and assist you, the individual impacted by COPD, to live as active, healthy and independent as possible. If you have not been to our website recently, be sure to check out the Educational Materials page under our "Learn More" category. There is a lot to see, and even more to come.

John W. Walsh:



Prior to 2004, there was no organization focused on COPD as a chronic condition that affected tens of millions of Americans and hundreds of millions of people worldwide. The focus was limited to clean air and tobacco control; COPD was highly stigmatized with the "shame and blame" of a self-inflicted disease. Individuals avoided the diagnosis, were embarrassed to be labeled with emphysema or chronic bronchitis and were given no hope of any recovery or any improved quality of life. There was no place to go for understandable, accurate and consistent information and there was very little public support for research and limited therapeutic options.

The COPD Foundation was founded in 2004 by individuals with COPD and leadership from the scientific and clinical community to focus exclusively on the mission to prevent and cure COPD and to improve the lives of all people affected by it. This unique partnership remains steadfast to this day and has expanded to include all stakeholders related to COPD. Without the dedication and commitment of these individuals and the seed funding and collaboration from the Alpha-1 Foundation, we would not have made the incredible progress that we have in the past 10 years.

Since inception, the COPD Foundation has maintained a strategic plan on how best to embrace and expand our three areas of focus: 1. Research 2. Education 3. Public policy and advocacy. We have created the infrastructure to support the research community and accelerate targeted therapeutic development. We have established scientific credibility and cre-

ated a balanced platform for federal agencies, academic medical research, community and industry to work together to support better diagnosis, improved treatment and development of new therapies to improve the quality of lives for individuals with COPD.

The COPD Foundation's active involvement and coordination of additional industry support for the COPDGene® Study gave us the ability to follow everyone longitudinally. Without question, the creation of this unique public-private partnership was a critical element in the renewal of funding from the National Heart, Lung and Blood Institute (NHLBI). This is the largest group of individuals ever studied and the largest grant ever awarded for lung disease, and the COPD Foundation is an integral part of its success under the leadership of Drs. James Crapo and Edwin Silverman.

The COPD Foundation was able to respond to the NHLBI's referral of interest about supporting bronchiectasis research by convening a group of experts and creating the Richard H. Scarborough Bronchiectasis Research Consortium and Registry. This has established the largest registry in the world of non-CF related bronchiectasis patients and networked numerous institutions focused on improving health outcomes and targeted therapies. It has also supported the impetus for bio-tech and pharmaceutical companies to initiate drug development for bronchiectasis in their pipeline.

When the Food and Drug Administration (FDA) needed a platform to take on the challenge of biomarker qualification for COPD, they came to the COPD Foundation. We convened a workshop on COPD biomarkers that resulted in a consensus recommendation to organize a COPD Biomarker Qualification Consortium (CBQC) and the COPD Foundation coordinated the collaboration of five pharmaceutical companies, the NHLBI and several academic studies to create an integrated data base of up to 120,000 study subjects to support the qualification of biomarkers that should accelerate therapeutic development and approval.

Our CBQC currently has three biomarker qualifications in progress and identified the



This article is special for the COPD Foundation's 10-year anniversary.

Continues on Page 22

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next three after convening the second workshop in 2013. This historic collaboration involving scientists from academia, industry and government would not have happened without the COPD Foundation.

There are numerous other examples of the progress we've made in research that we've reported on in the *Digest* and for which we will continue to keep the COPD community aware. Our immediate challenge and absolute priority is to create the largest registry of individuals with COPD ever assembled. We were thrilled to be awarded a Patient Centered Outcomes Research Institute (PCORI) Patient Powered Research Network (PPRN) contract to create a registry of 50,000 Americans with COPD over the next eighteen months. This may seem like a "mission impossible," but we're absolutely committed to proving this wrong and we are confident that the community will step up to the plate and join this incredible initiative. (Please call the C.O.P.D. Information Line at 866-316-COPD for information). Just imagine what we can accomplish with hundreds of thousands engaged in supporting our efforts.

Ten years ago there was barely any information available about COPD. Since then, the COPD Foundation has become an integral part of the NHLBI's *Learn More, Breathe Better Campaign*, establishing two key programs to support the campaign in 2007. The C.O.P.D. Information Line makes over 5,000 contacts a month, and all of the associates are fully trained individuals living with COPD or caregivers who provide the most direct resource ever for individuals affected by COPD. Our Mobile Spirometry Unit (MSU) generated awareness and has screened over 100,000 individuals across America. Our biggest impact with our MSU was the realization that you can test your lungs like you can test your blood pressure, cholesterol or blood sugar levels. Without the MSU, we would not have been able to conduct the Case Finding Validation Study. This study was recommended from our Case Finding Workshop we co-sponsored with the NHLBI. As a result of the findings and publication of this study, the COPD Foundation is now part of a grant from the NHLBI led


by Dr. Fernando Martinez to create new, more accurate screeners and protocol to ensure the 12-14 million Americans who are symptomatic but not yet diagnosed with COPD can receive a proper diagnosis.

The DRIVE4COPD campaign has created the momentum to vastly expand awareness of COPD across America. We have engaged corporate America with our Employer Toolkit and are using the data from the *COPD Uncovered Study* that reported a majority of those with COPD are still in the workforce. Embedding our COPD message in corporate wellness programs and adding our risk screener to annual health risk assessment tools should help more people get diagnosed earlier. We've had more public exposure to COPD through the NASCAR collaboration than ever. To date, more than 3 million Americans have completed the five-question Risk Screener.

We have reported regularly about our public policy and advocacy initiatives in the *Digest* and many of you have signed on as state captains. We know that we can impact Congress; we know that we can impact access and support choice; and we have made great strides in all of this. And it's because of you, the COPD community. You've stepped up and made these things happen, and change, beneficial change, has come to the COPD Foundation and to all of you.

As I look back on the past 10 years, it's hard to believe that so much has been accomplished in a seemingly short amount of time. The resources, education, research, advocacy and community that exist now is overwhelming and thriving. We are so proud of everything the COPD Foundation has been able to do, and we look forward to the next 10 years and beyond.

We will continue to increase our resources, programs, educational materials, and events, and will work tirelessly to engage everyone in the COPD community. We welcome you to join our registry, become an advocate, and help us spread awareness for COPD.

To learn more, or to become involved in any capacity with the COPD Foundation, please visit our website at: www.copdfoundation.org 

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Remembering Phil Everly

Patti Everly remembers her husband, Phil Everly, as a gracious, lovable, family man who did whatever he could to help people.

"He was proud of his accomplishments, but he never thought he did enough. He was amazingly talented, and just the most beautiful singer I ever heard," she says. "He was a compassionate, selfless person, and left behind an incredibly loving family, amazing music that will last forever, and a beautiful voice that was silenced by a horrible disease."

Phil Everly, half of the vocal duo the Everly Brothers, passed away January 3, 2014, from complications of COPD.

Phil and his brother Don are credited to be "the most revered vocal duo of the rock-music era, their exquisite harmonies profoundly influencing the Beatles, the Beach Boys, the Byrds, and countless younger-generation rock, folk and country singers," according to the Los Angeles Times.

"He was a family man above all else. He was always making sure everyone was taken care of. Even when he was sick, he was still worried about everyone else," Patti says. "He was a super funny guy; he could never be serious for too long. Our lives were just trying to make each other laugh."

Patti says as they grew older, they enjoyed spending time together, and with their family. Phil had two sons from previous marriages, and they were very careful.

Family always came first for Phil, and Patti says spending time with his grandchildren meant the world to him.

"At first, when they saw Phil's oxygen, they were a tiny bit taken aback, but we'd just say, 'Don't step on Grandpa's oxygen,' and they were very careful."

John N. McAtee, M.D., a pulmonologist in Gulf Shores, Ala., was Phil's doctor since 2008.

"When I first met him, he never let on who he was. Once I saw his name, I knew exactly who he was, but he never said anything, even after several visits. He was a big-time celebrity, but in reality, he never had airs about him, and was an incredible person," McAtee says. "As a COPD patient, he knew that you had to take care of the body around the sick lungs, too. Patti was very much into that, and gave him a great deal of encouragement."



Patti and Phil Everly, on an anniversary

As a patient, Dr. McAtee says Phil loved life, and truly appreciated all of those around him.

"As famous as he was, he was so appreciative of every little thing you did for him. That was just him. He was a real person, and a good guy. He paid attention to details," Dr. McAtee says. "I hope that [his legacy] can enlighten the need to know about how devastating lung disease can be, and how delicate life is. Every day, you should pay attention to details."

Patti says that without Dr. McAtee's kindness and expertise, she doesn't think Phil would have lived as long as he did.

Patti and Phil met in 1994. Patti says she recalls that Phil, who quit smoking in 2001, was smoking during their first date.

"I remember he was smoking during the meal, and he put out the cigarette. And then I put my gum in the same ashtray, and it got tangled up with his cigarette, and my gum got on the waiter's hand and the menu," Patti recalls. "I remember he kind of looked at me funny, and I just thought to myself, 'This is not how I wanted the date to go.' I just couldn't believe it."

Patti didn't need to worry too much; the pair married in 1999.

Since Phil had spent his life helping people, Patti thought it was fitting to reach out after his death to help others, in his name. That's when she contacted

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One of Patti's favorite photos of Phil

the COPD Foundation, and together, they created the Phil Everly Memorial Fund.

(www.copdfoundation.org/PhilEverlyMemorial)

"He was always so good to other people, and charitable. That's why this is so perfect," she says.

During Phil's last stay in the hospital, Patti says he was still always more concerned about her and their family than he was himself.

"He was always saying, 'Get out there, go have fun.' I think he knew in the last month that he was dying, and didn't want me to worry. I could see he was so short of oxygen," Patti says. "He still had so many songs to write to set people free. He was all about setting other people free."

She says as his caregiver, she wants all caregivers out there to know that they do a remarkable job, and her heart goes out to them.

"It's a tough job, and I want to give a shout out to those people, because my job is over, but they're still out there, doing it everyday," Patti says. "My 81-year old mother was also diagnosed with mild COPD two years ago and is on oxygen part-time, so my job goes on."

"Phil always said he didn't want people sitting around and crying [at his funeral], he wanted people to laugh and tell stories. His take on death was that he believed nobody dies. That you just go in another room at the party," Patti says. "He said that people just go to another room, and wait for everyone else to arrive. He just got to the party earlier than the rest of us." ❀

The COPD Foundation would like to express our heartfelt condolences to Patti Everly and her family on the loss of her husband, Phil Everly. We are grateful to them for extending his legacy by making a commitment to support our efforts to eradicate this disease. We are motivated by their support to continue to make progress through research to ultimately find a cure for COPD, so individuals such as Phil will not have to suffer.

The Everly family would like contributions to be made in memory of Phil to the COPD Foundation, to help us fight this terrible disease.

Please visit www.COPDFoundation.org/PhilEverlyMemorial for more information.

E-Cigarettes: Not a Safe Alternative

By: Samantha Hillson, M.A., M.P.H., Tompkins County Health Department

“Take back your freedom,” “the smart alternative to cigarettes,” “rewrite the rules,” “crafted for use anytime, anywhere” are just some of the slogans that are seen in E-cigarette advertisements.

Electronic cigarettes (e-cigs) are becoming increasingly popular and available. The marketing tactics used by e-cigs and tobacco companies are reaching staggering heights because these devices are entirely unregulated by the Food and Drug Administration (FDA). As a result, millions of dollars are being spent on television commercials with celebrities, radio spots and even sports sponsorships. The use of television for marketing traditional cigarettes was banned almost 50 years ago. Blu eCigs, an e-cigs company purchased by Lorillard, Inc. (the manufacturer of Newport cigarettes) in 2012 for \$135 million, spent \$12.4 million on ads in major media in the first quarter of 2013, according to the New York Times. E-marketing messages suggest that e-cigs are safer for your health and allow people to evade the smoking bans in workplaces, restaurants and other places that have defined much of the last decade.

E-cigs first entered the market ten years ago in China and subsequently around the world and in the United States by 2007. E-cigs use liquid nicotine cartridges that are heated to produce a vapor. Nicotine, also used in pesticides, can raise blood pressure and is toxic in large doses. Many people may think that the vapor is harmless, just water vapor, but this is not true. The chemicals needed to produce the vapor are not necessarily safe for inhalation and contain known carcinogens—cancer causing agents, including nitrosamines and formaldehyde. Until the FDA completes appropriate studies, absolute health risks are unknown.

The motivation and reasons for using e-cigs vary from person to person. Some individuals use e-cigs as a substitute or alternative when they are in a location where smoking is banned, such as indoors or in a public space, but continue to use tobacco cigarettes in unrestricted areas. This use of both conventional cigarettes and e-cigs is referred to as “dual use.” Other users perceive these devices to be less harmful than conventional cigarettes and may try to use e-cigs as a cessation tool. There are different nicotine levels in cartridges, so people can control their intake of nicotine and even reduce to nicotine-free cartridges. However,


e-cigs are not currently regulated as cessation devices.

Many people, especially youth, are intrigued by this new technology that can be acquired as yet another gadget to plug in. Young people are asking about e-cigs and “vaping” (the action of using an e-cigs); they are curious and confused about these products. Youth are being inundated by marketing at local groceries and gas stations that offer discounts and give-a-ways for e-cigs starter kits. Despite what our kids are learning about the dangers of tobacco use, all the tobacco marketing they see teaches them that smoking is normal, accessible, and cool. The same strategies apply to e-cigs products, most of which look like traditional cigarettes.

In September 2013, the Centers for Disease Control and Prevention (CDC) released a report that e-cigs experimentation doubled among U.S. middle and high school students between 2011 and 2012. Furthermore, many of the students who tried e-cigs have never smoked a conventional cigarette. This poses a great risk to young people who know the dangers of traditional cigarettes, but are enticed by e-cigs. Concerns include: the negative impact of nicotine on adolescent brain development, the risk for nicotine addiction, and the initiation of using traditional cigarettes.

Therefore, as a society, we must ask ourselves what the future holds. Ten years ago these products did not exist and now they are quickly becoming abundant. Urgent action is warranted. A handful of states and municipalities have taken the basic step of setting a minimum purchase age of 18 years old, but much more needs to be done.

People living with lung disease like asthma or COPD, are known to be susceptible to the effects of inhalation irritants of any kind, not just tobacco smoke. Therefore, individuals with lung disease should avoid inhaling any foreign substances into the lungs whether this is tobacco smoke, vapors from e-cigs, wood smoke from fireplaces, bio-mass pollution, or other known triggers. In fact, the only way to assure “safety” of your lungs is to protect them throughout your entire life. Kids take note, *don't smoke anything.*

This is an important conversation to have in our communities. Share your ideas about e-cigs by writing to your elected officials, your local newspaper, or calling the C.O.P.D. Information Line: (866) 316-2673. 



This article is special for the COPD Foundation's 10-year anniversary.

COPD Foundation PEP Program – Helping Pulmonary Rehabs

By Jane Martin, BA, L.R.T., C.R.T.

The COPD Foundation's mission is to "Prevent and cure chronic obstructive pulmonary disease and to improve the lives of all people affected by COPD." In addition to its already wide array of programs, the COPD Foundation has taken another step to fulfill this mission with a unique new program, PEP (Pulmonary Education Program). Launched just 15 months ago, PEP now supports pulmonary rehabilitation (pulmonary rehab) programs in 208 pulmonary rehab centers in 43 states across the United States!

Why PEP?

COPD is a complex disease. For individuals impacted by this disease, there's a lot to learn about so many aspects of COPD management. At the same time, pulmonary rehab programs are often challenged by meager revenues and high operating costs. Many programs struggle to provide basic chronic lung disease education, and are simply unable to take the next step - to provide high-quality, up-to-date, disease-specific patient education materials to their COPD patients. Through PEP, the COPD Foundation addresses both issues, providing pulmonary rehab programs with high quality COPD patient educational materials which help patients better understand their disease. PEP is free of charge.

Starting Pulmonary Rehab

Individuals with physician-diagnosed COPD who enter a PEP pulmonary rehab receive a duffel bag with a variety of COPD information including a set of 10 Slim Skinny Reference Guides® (SSRG). The SSRG's are booklets (no more than 16-pages each) with easy-to-understand, disease-specific information. Topics range from medications and nutrition to coping and end-of-life issues. The newest SSRG, *COPD in the Hospital and the Transition Back to Home* is also part of the package.

"The patient welcome packet has received great reviews and the Skinny guides are especially nice because they are topic-specific, making it easy for patients to pick and choose topics they are interested in reading about." -

Linda McCabe Pinn, M.S.N., R.N., RCP, PEP
Coordinator for the PEP at Illinois Valley
Community Hospital in Peru, Illinois

Graduating from Pulmonary Rehab

At graduation, pulmonary rehab participants with COPD receive a copy of the *Sit and Be Fit for COPD* video with exercises that can be easily modified by a range of users—those more physically able as well as those who are significantly limited. In addition to the video, the packet holds other information including *Live Your Life with COPD-52 Weeks of Health Happiness and Hope*, guiding graduates to explore one topic each week for ongoing, long-term success in managing COPD.

"The exercise video is completely geared to the COPD patient. The instructor makes it fun and is also very motivational." -McCabe Pinn

Post-graduate Support

PEP also offers pulmonary rehab graduates the opportunity to continue with education and support through the *On Track with COPD Ongoing Support Program*. Participating in pulmonary rehab can help people with COPD feel so much better, while improving endurance, strength and the ability to manage COPD. But it's not always easy to stay motivated, and remember everything learned. Left on their own, pulmonary rehab graduates can slip back to inactivity and exacerbations within 6-10 months, landing them right back where they started.

The *On Track* program does just what it says, help graduates stay on track through monthly calls with questions and discussions tailored especially for them.

Support for Staff

PEP supports not only pulmonary rehab participants, but also staff members with a **wealth of COPD and program management information** to assist them in their work. The COPD Foundation hosts four webinars every year, with PEP program updates and an educational presentation with AARC's Continuing Respiratory Care Education (CREC). PEP centers have the opportunity to host a **COPD Community Education Workshop** in their local community. This dual-track event allows local health care professionals to learn more about COPD and obtain continuing education credits. The patient education track exposes participants to strategies for better management of COPD and encourages social interaction in a positive environment. In addition, PEP coordinators may order

free **COPD educational materials with free shipping** for in-patient education, health fairs, etc.

What's Ahead?

The COPD Foundation plans to expand the PEP section of their website this year, and include an interactive map with the locations of all PEP centers. A COPD Support Group Network will also be launched, and a PEP Coordinator Community will be put in place to encourage the exchange of information and support between pulmonary rehab staff members.

For more information on anything PEP-related, please contact Jane Martin at: jmartin@copdfoundation.org.

Many thanks to Linda McCabe Pinn, M.S.N., R.N., R.C.P PEP Coordinator for the Pulmonary Rehab Program at Illinois Valley Community Hospital in Peru, Illinois for sharing her experience with PEP.

Get Your COPD Advocacy Drivers License



Why should I Become a Certified COPD Advocate?

The most powerful advocates are those who understand our advocacy message and know what to say to their elected officials to promote good COPD public policy. The 30 minute training video will prepare COPD advocates for meetings with their elected officials, explain how things get done in Washington, and lay out the COPD Foundation's advocacy strategy so our advocates are prepared and knowledgeable. Visit the COPD Foundation website to watch the training video and get your COPD advocacy drivers license today!

Watch the Training Video at www.copdfoundation.org
Take Action at www.operation435.org

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